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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
NIEBAUER, RONALD T	

ART UNIT	PAPER NUMBER
1654	

MAIL DATE	DELIVERY MODE
08/05/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/559,996	KRAHMER ET AL.	
	Examiner	Art Unit	
	RONALD T. NIEBAUER	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 May 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *4-12 and 15-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,13-14,21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/18/09 has been entered.

Applicants amendments and arguments filed 5/18/09 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed is herein withdrawn.

As stated previously, applicants elected Group I and the species, where Z is formula Xc (see specification page 15) in which b is 2, c is 2, d is 3, P is H and R1 is C5 alkoxy residue; W is hydrogen; X is CH3-(O-CH2CH2)3-OH wherein X is attached through the OH group; V is tetraethylene glycol. The species has been interpreted as being of formula Ia since there is no X in formula Ib. Since the valency of oxygen would not be proper (oxygen would be bonded to a carbon, hydrogen, and nitrogen) as stated by applicant, the X has been taken to be attached via the O (not an OH) such that the oxygen is bonded to a nitrogen and carbon. The elected species was found to be free of the prior art. In accord with section 803.02 of the MPEP the search was then extended to other species and art was found that reads on species of the instant claims. As such, the examination has been extended to the extent necessary to determine patentability of the Markush-type claim. Further section 803.02 of the MPEP states that the prior art search, however, will not be extended unnecessarily to cover all nonelected species.

It is noted that the claim listing provided by the applicant on 5/18/09 states that claim 21 is withdrawn. However, claim 21 was examined in the previous office action (1/16/09). In order to advance prosecution, claim 21 has been included in the instant examination since art cited herein reads on claim 21. Claim 3 has been included in the instant examination since art cited herein reads on claim 3.

In the instant case, claims 6-8,16 are in different groups than the elected group. In the instant case, claims 4-5,9-12,15,17-20 include other features than the originally elected species and the cited art does not read on the claims.

Claims 6-8,16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 4/15/08.

Claims 4-5,9-12,15,17-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 4/15/08.

Claims 1-3,13-14,21are under consideration.

Claim Rejections - 35 USC § 102

Claims were previously rejected under 102 based on the Rathore reference. Since the claims have been amended the rejection has been updated.

The rejection based on Biessen et al. (WO 94/04545) is a new rejection.

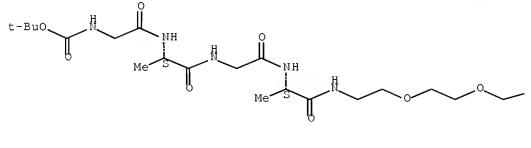
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

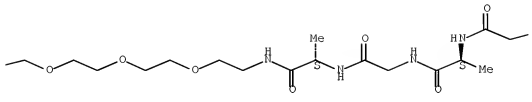
Claims 1-3,13-14,21 are rejected under 35 U.S.C. 102(b) as being anticipated by Rathore et al. (Journal of Polymer Science , Part A:Polymer Chemistry, 2000 v38(2) pages 352-366; first cited on 6/25/08).

Rathore teach copolymers containing polyethylene glycol segments and peptide segments (abstract). In scheme 1 (page 357) Rathore teach structure 6 (Boc-GAGA-HN(CH2CH2O)5-CH2CH2NH-AGAG-Boc). It is noted that the structures of the amino acids of structure 6 are shown in chart 1 (page 353) and scheme 2 for example. Structure 6 of Rathore is:

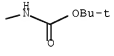
PAGE 1-A



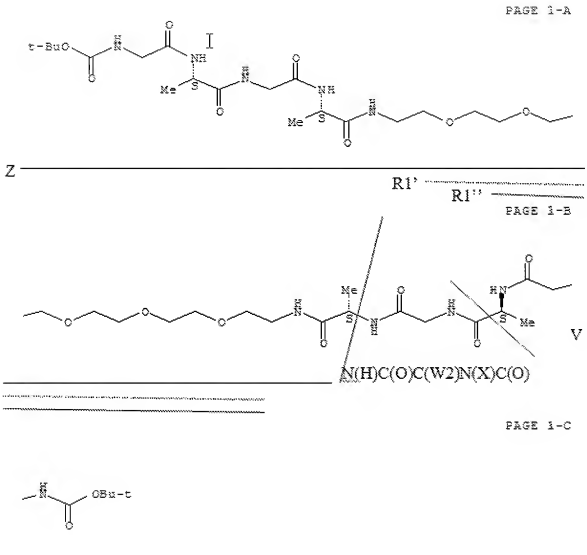
PAGE 1-B



PAGE 1-C



Below is a marked up structure relating the structure of Rathore to the instant claims.



In comparison to the instant invention the compound of Rathore is of formula Ia of claims 1,21 of the instant invention. Specifically, Z (see the above structure label 'Z') is Boc-Gly-Ala-Gly-Ala-NH-(CH2CH2O)5-CH2CH2NH-C(O)C(CH3). Thus Z is a hydrocarbon residue which contains heteroatoms as recited in the instant claims. Further the compound of

Rathore includes N(H)C(O)C(W2)N(X)C(O) (see above) as in formula Ia of the instant invention. Each occurrence of W is hydrogen. Each occurence of X is hydrogen. V is C(CH3)NHC(O)-CH2-NH-C(O)-Boc. Thus V is a hydrocarbon residue which contains heteroatoms as recited in the instant claims. Further, the claims recite that the residues V,W,X, and Z together comprise at least two residues which have formula IIa. In the instant case, Z comprises at least two residues which have formula IIa: CH2-O-CH2CH2-O-(CH2-CH2-O)3-CH2-CH2 (which is labeled as R1' above) where R1 is a hydrocarbon with 1 to 10 carbon atoms with heteroatoms as recited in the instant claims; CH2-O-(CH2-CH2-O)3-CH2-CH2 (which is labeled as R1'' above) where R1 is a hydrocarbon with 1 to 10 carbon atoms with heteroatoms as recited in the instant claims.

It is noted that claim 3 recites that the compound comprises at least 3 residues which have formula IIa. In addition to R1' and R1", the compound of Rathore also comprises CH2CH2-O-(CH2-CH2-O)3-CH2-CH2 thus meeting the limitation of claim 3.

It is noted that claim 2 recites that Y (which can be a part of any of V,W,X, and Z) is able to bind a wide range of groups. Although the office has no facility to test the binding capabilities of the compound of Rathore, due to the variety of groups contained in the compound of Rathore there is a reasonable basis that the compound meets the limitations of claim 2, absence evidence to the contrary. Scheme 2 (page 357) shows that the NH residues, for example, can act in hydrogen bonding and as such the compound contains a binding group Y thus meeting the limitations on Y recited in claims 1,21 of the instant invention. The compound of Rathore meets the structural limitations of claims 1,21 of the instant invention.

Rathore teach (page 355 1st column last two paragraphs) the synthesis of structure 6 in solution so the compound is necessarily part of a composition thus meeting the structural limitations of claims 13-14 of the instant invention. It is noted that the recitation of 'diagnostic' in claim 14 does not result in a structural difference. As such Rathore meet the limitations of claims 1-3,13-14,21 of the instant invention.

Response to Arguments 102 rejection Rathore

Since the claims have been amended, a new rejection adapted to the claims is recited above using the same reference as in the previous rejection. Applicants arguments will be considered to the extent that they apply to the current rejection and claim set.

Applicants argue that the compound of Rathore does not have Formula IIa or have R1 as claimed.

Applicants note that the examiners structure includes what appears to be sulfur atoms.

Applicant's arguments filed 5/18/09 have been fully considered but they are not persuasive.

Although Applicants argue that the compound of Rathore does not have Formula IIa or have R1 as claimed, as discussed and shown above the compound of Rathore meets the claim limitations. It is noted that the claims recite that the residues V,W,X, and Z together comprise at least two residues which have formula IIa. However, applicants arguments appear to assert that R1 of formula IIa must include all of Z. However, from the claim language 'Z… comprise at least…' it is clear that Z can encompass more than just formula IIa (see also MPEP section 2111.03). In fact, the claims state that Z can be a hydrocarbon residue which can contain heteroatoms. Further, it is noted that in accord with section 2111 of the MPEP that the claims are

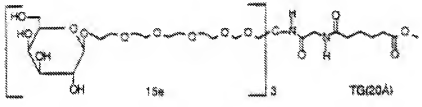
to be given the broadest reasonable interpretation. The claims state 'comprise at least two residues which have formula IIa'. As discussed above, such claim limitations are met. Although applicants arguments seem to imply that the claims are drawn to two independent (and non-overlapping) occurrences of formula IIa, such language does not appear in the claims. In the instant case, the claims refer to 'residues' which have formula IIa. In the chemical arts, a 'residue' is recognized as a structural element. As such, any multi-component compound would include numerous residues. In the instant case, there is no basis to read extra limitations into the claims.

Although Applicants note that the examiners structure includes what appears to be sulfur atoms, it is first noted that Rathore teach structure 6 (Boc-GAGA-HN(CH2CH2O)5-CH2CH2NH-AGAG-Boc) in scheme 1 (page 357) and the structures of the amino acids of structure 6 are shown in chart 1 (page 353) and scheme 2 for example. There are no sulfur atoms in the structure of Rathore. The structure drawing does show the stereochemistry. In the chemical arts, stereochemistry is concerned with the three-dimensional aspects of molecules. An 'S' does appear at certain carbon atoms in the structure to denote stereochemistry using the R (Latin rectuis "right") and S (Latin sinister "left) assignments. In fact, the locations where an 'S' notation appears also include a dash or wedge to denote the stereochemistry. The locations where an 'S' notation occur are at points where lines come together indicating a carbon atom. In contrast, compare the occurrence of nitrogen molecules (N) in which the 'N' appears between lines (i.e. –N-).

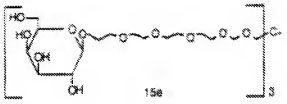
The rejection based on Biessen et al. (WO 94/04545) is a new rejection.

Claims 1-3,13-14,21 are rejected under 35 U.S.C. 102(b) as being anticipated by Biessen et al. (WO 94/04545).

Biessen teach triantennary cluster glycosides, their preparation and use (abstract). On page 12 of the drawings Biessen teach a compound called TG(20A) of structure:



In comparison to the instant invention the compound of Biessen is of formula Ia of claims 1,21 of the instant invention. Specifically, Z includes the repeating structural element along with a CH2, that is Z is

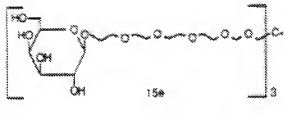


Thus Z is a hydrocarbon residue which contains heteroatoms as recited in the instant claims. Further the compound of Biessen includes N(H)C(O)C(W2)N(X)C(O), that is

Thus the compound of Biessen includes N(H)C(O)C(W2)N(X)C(O) as in formula Ia of the instant invention. Each occurrence of W is hydrogen. Each occurence of X is hydrogen.

V is

Thus V is a hydrocarbon residue which contains heteroatoms as recited in the instant claims. Further, the claims recite that the residues V,W,X, and Z together comprise at least two residues (or three residues, see claim 3) which have formula IIa. In the instant case, Z is



It is noted that the number '3' in the structure means that the structural element enclosed in brackets in repeated 3 times. Thus, the compounds contains 3 occurrences that include CH-O-(CH2-CH2-O)3-CH2CH2 thus meeting the limitations of the instant claims.

It is noted that claim 2 recites that Y (which can be a part of any of V,W,X, and Z) is able to bind a wide range of groups. Although the office has no facility to test the binding capabilities of the compound of Biessen, due to the variety of groups contained in the compound of Biessen there is a reasonable basis that the compound meets the limitations of claim 2, absence evidence to the contrary.

Biessen teach (page 355 1st column last two paragraphs) the use of compound TG(20A) in assays for example (page 21 line 25) so the compound is necessarily part of a composition thus meeting the structural limitations of claims 13-14 of the instant invention. It is noted that the recitation of 'diagnostic' in claim 14 does not result in a structural difference. As such Biessen meet the limitations of claims 1-3,13-14,21 of the instant invention.

Double Patenting

This rejection is a new rejection.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3,13-14,21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-27 of copending Application No. 11/993,425 ('425). Although the conflicting claims are not identical, they are not patentably distinct from each other.

'425 teach compounds (claim 11) of the same general formula of the instant compounds (see instant claims 1,21). '425 teach formula IIa (claim 1) as in the instant claims as well as multiple groups of formula IIa (claim 3) (see instant claim 3 for example). '425 teach compositions with the compounds (claim 19) (see instant claims 13-14 for example).

It is noted that claim 2 recites that Y (which can be a part of any of V,W,X, and Z) is able to bind a wide range of groups. Although the office has no facility to test the binding capabilities of the compound of '425, due to the variety of groups contained in the compound of '425 there is a reasonable basis that the compound meets the limitations of claim 2, absence evidence to the contrary.

'425 teach the compounds as part of a composition thus meeting the structural limitations of claims 13-14 of the instant invention. It is noted that the recitation of 'diagnostic' in claim 14 does not result in a structural difference.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims are directed to an invention not patentably distinct from claims of commonly assigned 11/993,425 as discussed above.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned 11/993,425, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RONALD T. NIEBAUER whose telephone number is (571)270-

3059. The examiner can normally be reached on Monday-Thursday, 7:30am-5:00pm, alt. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Anish Gupta/
Primary Examiner, Art Unit 1654

/Ronald T Niebauer/
Examiner, Art Unit 1654